ALKA-SELTZER PLUS DAY AND NIGHT SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and doxylamine succinate
Bayer HealthCare LLC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Alka-Seltzer Plus ® Day & Night Severe Cold and Flu

Alka-Seltzer Plus ®
Severe Cold + Flu Day

Drug Facts

Active ingredients (in each packet)	*Purposes*
Acetaminophen 500 mg	Pain reliever/fever reducer
Dextromethorphan hydrobromide 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant
Phenylephrine hydrochloride 10 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold or flu:
  - minor aches and pains
  - headache
  - sore throat
  - cough
  - nasal congestion
  - sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 packets in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after

stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

Ask a doctor before use if you have
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough with excessive phlegm (mucus)

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not exceed recommended dosage

Stop use and ask a doctor if
- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.
- nervousness, dizziness, or sleeplessness occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions
- do not take more than the recommended dose
- take every 4 hours; do not exceed 6 packets in 24 hours or as directed by a doctor
- adults and children 12 years and over: dissolve contents of one packet in 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes.
- children under 12 years: do not use

Other information
- **each packet contains:** potassium 5 mg and sodium 6 mg
- store at room temperature

Inactive ingredients

acesulfame potassium, anhydrous citric acid, compressible sugar, D&C yellow #10, dental-type silica, FD&C red #40, flavors, maltodextrin, povidone, pregelatinized starch, silicon dioxide, sodium citrate, stearic acid, sucralose, tartaric acid, tribasic calcium phosphate

Questions or comments?

1-800-986-0369 (Mon-Fri 9AM - 5PM EST)

Alka-Seltzer Plus ®
Severe Cold + Flu Night

Drug Facts

Active ingredients (in each packet)	*Purposes*
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan hydrobromide 20 mg	Cough suppressant
Doxylamine succinate 12.5 mg	Antihistamine
Phenylephrine hydrochloride 10 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold or flu:
  - headache
  - minor aches and pains
  - cough
  - sore throat
  - nasal congestion
  - sinus congestion and pressure
  - runny nose
  - sneezing
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 5 packets in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use to sedate children.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

Ask a doctor before use if you have

- liver disease

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product
- **do not exceed recommended dosage**
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if
- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.
- nervousness, dizziness, or sleeplessness occurs

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- children under 12 years: do not use

Other information
- **each packet contains:** potassium 5 mg and sodium 5 mg
- store at room temperature

Inactive ingredients

acesulfame potassium, anhydrous citric acid, compressible sugar, D&C yellow #10, dental-type silica,

FD&C red #40, flavors, pregelatinized starch, sodium citrate, sucralose, tartaric acid, tribasic calcium phosphate

Questions or comments?

1-800-986-0369 (Mon-Fri 9AM - 5PM EST)

Dist. by: Bayer HealthCare LLC
Whippany, NJ 07981

PRINCIPAL DISPLAY PANEL - Kit Carton

Alka-Seltzer
PLUS ®

SEVERE COLD + FLU

Honey Lemon Zest
Fast Relief Mix-In Packets

DAYNON-DROWSY

Acetaminophen / Pain reliever-fever reducer

Phenylephrine HCl / Nasal decongestant

Dextromethorphan HBr / Cough suppressant

Guaifenesin / Expectorant

• ***Nasal Congestion***

• ***Headache & Body Ache***
• ***Cough • Sore Throat• Mucus***

• ***Fever •Chest Congestion***

NIGHT

Acetaminophen / Pain reliever-fever reducer

Doxylamine succinate / Antihistamine

Phenylephrine HCl / Nasal decongestant

Dextromethorphan HBr / Cough suppressant

• ***Nasal Congestion***

• ***Headache & Body Ache***
• ***Cough • Runny Nose***
• ***Fever • Sore Throat***

6 DAY PACKETS + 6 NIGHT PACKETS

12 TOTAL

ALKA-SELTZER PLUS DAY AND NIGHT SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and doxylamine succinate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-0924

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0924-12	1 in 1 CARTON; Type 0: Not a Combination Product	07/01/2014	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	6
Part 2	6 PACKET	6

Part 1 of 2

ALKA-SELTZER PLUS DAY SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride powder, for solution

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
HONEY (UNII: Y9H1V576FH)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TARTARIC ACID (UNII: W4888I119H)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
SUCROSE (UNII: C151H8M554)	
MENTHOL (UNII: L7T10EIP3A)	
LEMON (UNII: 24RS0A988O)	

Product Characteristics

Color	yellow	**Score**	
Shape		**Size**	
Flavor	LEMON, HONEY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2014	

Part 2 of 2

ALKA-SELTZER PLUS NIGHT SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride powder, for solution

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TARTARIC ACID (UNII: W4888I119H)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
SUCROSE (UNII: C151H8M554)	
MENTHOL (UNII: L7T10EIP3A)	
LEMON (UNII: 24RS0A988O)	
HONEY (UNII: Y9H1V576FH)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	yellow	**Score**	
Shape		**Size**	
Flavor	HONEY, LEMON	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2014	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 1/2020 Bayer HealthCare LLC.